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EXAMINER	
NOGUEROLA, ALEXANDER STEPHAN	
ART UNIT	**PAPER NUMBER**
1753	

DATE MAILED: 08/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/083,845	ARMSTRONG, DANIEL	
	Examiner	Art Unit	
	ALEX NOGUEROLA	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 May 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-6,8-13,15 and 17-29* is/are pending in the application.

4a) Of the above claim(s) *18-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-6,8-13,15-17 and 22-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 February 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Rejections pending since the Office action of February 10, 2005

1. All previous rejections are withdrawn.

Response to Arguments

2. With respect to Durr Applicants assert, "Durr does not suggest a process for separating microbes from other microbes as recited in the independent claims." See page 21 of the amendment of May 16, 2005. The examiner respectfully disagrees. The first sentence of the Durr abstract states, "The method permits the non-destructive analytical detection and/or the quantification of viruses or viral particles (analytes) in a liquid sample matrix containing organic or inorganic minor constituents, in particular protein moieties and/or nucleotides and/or other viruses. [emphasis added]" The preamble to claim 1 of Durr states, "Method for the non-destructive analytical detection or quantification of viruses or viral particles in a liquid sample matrix containing organic or inorganic minor constituents, protein moieties, nucleotides, or other viruses, ... [emphasis added]." Durr discloses, "known viruses can be clearly differentiated by means of specific antibodies (MABs). Here the entire established immunological differentiation of viruses in direct combination with the separation of viruses in CE is

available." See col. 10:36-57. Durr also discloses different migration times for two different strains of the same virus. See Figures 11(a) and (b).

3. With respect to McCormick Applicants state, "in contrast to McCormick, the dilute polymer and the ampholyte of the present invention do not physically alter the microbes ... in fact, the independent claims recite processes for separating the microbes while maintaining the microbes intact." The examiner respectfully disagrees. Applicants' independent claim 15 requires "dying said sample with a dye that causes viable microbes/cells to be distinguished from non-viable microbes/cells." Is not dying cells a physical alteration of the cells? This step is in fact one example of McCormick's step of adding an agent to the cells. See col. 12:3-11, for example. Furthermore, from Applicants' specification it seems that "intact" has the more limited meaning of not lysing cells. See page 2, second full paragraph and the first paragraph of the "Summary of the invention", which begins on page 2. A major feature of McCormick is that intact cells, including viable cells, can be analyzed. See col. 2:16-29.

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 1, 3, 4, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ebersole et al. (US 5,578,460) ("Ebersole") in view of Johnson et al. (EP 077325 A2) ("Johnson"), the CAPLUS abstract of Barkas et al. ("Use of polyacrylamide gel electrophoresis for the preparation of oriented virus particle preparations," Doklady Akademii Nauk SSR (1979), 245(3), 736-9 (Biochem.) ("Barkas"), Silman (US 4,526,865) ("Silman"), and Catsimpoolas (US 4,375,401) ("Catsimpoolas')

Addressing claim 1, Ebersole discloses a process for separating and identifying intact microbes while maintaining the microbes intact comprising:

(a) obtaining sample comprising one or more intact microbes/cells from a substrate containing the microbes/cells (col. 21:5-36);

(b) introducing the sample into a passageway having a fluid therein (col. 6:24-27 and col. 22:39-40);

(c) separating the one or more microbes/cells the fluid by means of capillary electrophoresis so as cause the one or more microbes/cells to move in the fluid and to separate one from another and from other components in said sample while maintaining the microbes/cells intact (col. 6:27-29; col. 22:47-50; col. 22:63-65); and

(d) analyzing the separated intact microbes/cells so as identify the microbes/cells (col. 6:35-47; col. 6:66 – col. 7:16; col. 22:32-38; and col. 23:2-11).

Although Ebersole discloses adding polymer to the running buffer to modify the viscosity (col. 15:2-5) or to the inner capillary wall (col. 14:43-47) to reduce electroendosmosis, Ebersole does not disclose adding a dilute water soluble polymer that focuses the microbes in the passageway during the separating step. However, at the time of the invention it was known to use a gel while electrophoresis microbes/cells. See Barkas and the abstracts of Silman and Catsimpoolas. At the time of the invention it was also known to add to an electrophoresis capillary a dilute water-soluble polymer that focuses biomolecules in the passageway during the separating step. See, for example, col. 3:34 – col. 4:11 in Johnson. Thus, whether a separation medium is used, such as gel or water-soluble polymer, while separating the microbes/cells, barring a showing to the contrary, such as unexpected results, is just a matter of optimizing the separation of the microbes/cells as this was a known purpose for using gels or uncrosslinked polymer solution during electrophoresis. Whether the water-soluble polymer is "dilute" is just a matter of optimizing the sieving effect of the polymer.

Addressing claim 3, for the additional limitation of this claim see Figures 5a-5c in Ebersole.

Addressing claim 4, for the additional limitation of this claim see col. 15:38-55 in Ebersole

Addressing claim 22, for the additional limitation of this claim note that Johnson discloses at least hydroxyethylcelluslose. See col. 6:25-29. The other listed polymers were also used as electrophoresis separation media at the time of the invention. It was within the skill of one with ordinary skill in the art at the time of the invention to select the optimum separation polymer from known separation polymers.

6. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ebersole et al. (US 5,578,460) ("Ebersole") in view of Johnson et al. (EP 077325 A2) ("Johnson"), the CAPLUS abstract of Barkas et al. ("Use of polyacrylamide gel electrophoresis for the preparation of oriented virus particle preparations," Doklady Akademii Nauk SSR (1979), 245(3), 736-9 (Biochem.) ("Barkas"), Silman (US 4,526,865) ("Silman"), and Catsimpoolas (US 4,375,401) ("Catsimpoolas') as applied to claims 1-4 above, and further in view of the first page of "Streptococcus pyogenes" article downloaded from www.textbookofbacteriology.net/streptococcus.html ("Streptococcus pyogenes") and "The Bacteria Antibotics Can't Kill" downloaded from www.tigr.org/~btran/ENTEROCCUS.html ("Enterococcus faecalis").

Ebersole does not mention an animal substrate; however, it would have been obvious to one with ordinary skill in the art at the time the invention was made to use an animal substrate because Ebersole discloses the microbes streptococcus pyogenes

and enterococcus faecalis, which cause infections in humans. See "streptococcus pyogenes" and "enterococcus faecalis"

7. Claims 1, 3-6, 8-13, and 22-24 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Durr et al. (US 5,723,031) ("Durr") in view of Johnson et al. (EP 077325 A2) ("Johnson"), the CAPLUS abstract of Barkas et al. ("Use of polyacrylamide gel electrophoresis for the preparation of oriented virus particle preparations," Doklady Akademii Nauk SSR (1979), 245(3), 736-9 (Biochem.) ("Barkas"), Silman (US 4,526,865) ("Silman"), and Catsimpoolas (US 4,375,401) ("Catsimpoolas').

Addressing claim 1, Durr discloses a process for separating and identifying intact microbes (see in Applicant's specification page 9, first sentence of the fourth full paragraph: "Microbes such as bacteria, viruses and fungi ... [emphasis added]") while maintaining the microbes intact comprising:

(a) obtaining sample comprising one or more intact microbes/cells from a substrate containing the microbes (Table 1 in column 5);

(b) introducing the sample into a passageway having a fluid therein (col. 4:31-36 and Table 2 – Injection in column 5);

(c) separating the one or more microbes the fluid by means of capillary electrophoresis so as cause the one or more microbes to move in the fluid and to separate one from another and from other components in said sample while maintaining the microbes intact (col. 4:39-40; col. 5:24-27; claim 1 preamable; col. 10:36-57; and Figures 11(a) and (b)); and

(d) analyzing the separated intact microbes so as identify the microbes (col. 4:40-50 and col. 5:35-41).

Durr does not disclose adding a dilute water soluble polymer that focuses the microbes in the passageway during the separating step. However, at the time of the invention it was known to use a gel while electrophoresis microbes/cells. See Barkas and the abstracts of Silman and Catsimpoolas. At the time of the invention it was also known to add to an electrophoresis capillary a dilute water-soluble polymer that focuses biomolecules in the passageway during the separating step. See, for example, col. 3:34 – col. 4:11 in Johnson. Thus, whether a separation medium is used, such as gel or water-soluble polymer, while separating the microbes/cells, barring a showing to the contrary, such as unexpected results, is just a matter of optimizing the separation of the microbes/cells as this was a known purpose for using gels or uncrosslinked polymer solution during electrophoresis. Whether the water-soluble polymer is "dilute" is just a matter of optimizing the sieving effect of the polymer.

Addressing claim 3, for the additional limitation of this claim see Durr col. 4:31-61.

Addressing claim 4, for the additional limitation of this claim see Durr col. 4:40-53.

Addressing claim 5, "foot-and-mouth virus" is separated and analyzed. See Table 1 in column 5 in Durr. Also see col. 2:52-55.

Addressing claim 6, Durr discloses a process for diagnosing disease caused by microbes (see in Applicant's specification page 9, first sentence of the fourth full paragraph: "Microbes such as bacteria, viruses and fungi ... [emphasis added]") comprising:

(a) obtaining a sample comprising one or more intact microbes/cells from a substrate containing the microbes (Table 1 in column 5);

(b) introducing the sample into a passageway having a fluid therein (col. 4:31-36 and Table 2 – Injection in column 5);

(c) separating the one or more microbes the fluid by means of capillary electrophoresis so as to cause the one or more microbes to move in the fluid and to separate one from another and from other components in said sample while maintaining the microbes intact (col. 4:39-40; col. 5:24-27; claim 1 preamble; col. 10:36-57; and Figures 11(a) and (b)); and

(d) analyzing the separated intact microbes so as identify the microbes (col. 4:40-50 and col. 5:35-41).

Durr does not mention (i) obtaining the sample from an organism stricken with a disease caused by the microbes, (ii) associating the microbe with a disease so as to

diagnose the disease, (iii) and using in the fluid a dilute water soluble polymer that focuses the microbes in the passageway during the separating step.

As for obtaining the sample from an organism stricken with a disease caused by the microbes, although not mentioned by Durr it would have been obvious to do so because Durr states, 'The viruses can be identified directly from any sample matrix, for example, from biological material (serum, urine, cells, plasma, cell supernatant, aqueous humour, saliva, et cetera) ..." (col. 2:52-59) and exemplifies the invention by separating and identifying active foot-and-mouth virus (col. 6:21-61).

As for associating the microbe with a disease so as to diagnose the disease it is clear that the just cited portions of Durr that Durr intended his invention to be used in real –world settings to, for example, identify from a bodily fluid whether an ill person has foot-and-mouth disease.

As for using in the fluid a dilute water-soluble polymer that focuses the microbes in the passageway during the separating step, at the time of the invention it was known to use a gel while electrophoresing microbes/cells. See Barkas and the abstracts of Silman and Catsimpoolas. At the time of the invention it was also known to add to an electrophoresis capillary a dilute water-soluble polymer that focuses biomolecules in the passageway during the separating step. See, for example, col. 3:34 – col. 4:11 in Johnson. Thus, whether a separation medium is used, such as gel or water-soluble polymer, while separating the microbes/cells, barring a showing to the contrary, such as unexpected results, is just a matter of optimizing the separation of the microbes/cells as this was a known purpose for using gels or uncrosslinked polymer solution during

electrophoresis. Whether the water-soluble polymer is "dilute" is just a matter of optimizing the sieving effect of the polymer.

Addressing claims 8, and 13, for the additional limitations of these claims see Durr col. 4:31-61.

Addressing claims 9 and 12, Durr states, 'The viruses can be identified directly from any sample matrix, for example, from biological material (serum, urine, cells, plasma, cell supernatant, aqueous humour, saliva, et cetera) or from non-biological formulations (water, medicaments, soil samples, et cetera) (col. 2:52-59) and exemplifies the invention by separating and identifying active foot-and-mouth virus (col. 6:21-61), which infects animals and people.

Addressing claim 10, Durr discloses a process for determining the binding affinity (col. 10:36-38) of a drug/other substance with a microbe/cell (see in Applicant's specification page 9, first sentence of the fourth full paragraph: "Microbes such as bacteria, viruses and fungi ... [emphasis added]") comprising

(a) obtaining a sample comprising one or more intact microbes/cells from a substrate containing the microbes/cells (col. 2:52-59);

(b) combining the sample with a drug or other substance in a fluid media to form a suspension and to allow the microbe/cell to bind with the drug/other substance (col. 10:45-47 and col. 11:3-6);

(c) introducing the suspension into a passageway having a fluid therein (col. 10:46-49 and col. 11:6-7);

(d) subjecting the suspension to capillary electrophoresis so as to cause the microbes/cells, and drug/other substance and bound microbes/cells-drug/other substance to move in the fluid and to separate from one another while maintaining the microbes/cells, the drug/other substance and the bound microbes/cells-drug/other substance intact (claim 1 preamble; col. 10:45-57; and col. 11:6-21); and

(e) analyze the separated, intact bound microbes/cells-drug/other substance to determine their affinity for each other (col. 10:45-67; col. 11:16-19; and col. 12:16-21).

Durr does not disclose adding a dilute water soluble polymer that focuses the microbes in the passageway during the separating step. However, at the time of the invention it was known to use a gel while electrophoresis microbes/cells. See Barkas and the abstracts of Silman and Catsimpoolas. At the time of the invention it was also

known to add to an electrophoresis capillary a dilute water-soluble polymer that focuses biomolecules in the passageway during the separating step. See, for example, col. 3:34 – col. 4:11 in Johnson. Thus, whether a separation medium is used, such as gel or water-soluble polymer, while separating the microbes/cells, barring a showing to the contrary, such as unexpected results, is just a matter of optimizing the separation of the microbes/cells as this was a known purpose for using gels or uncrosslinked polymer solution during electrophoresis. Whether the water-soluble polymer is "dilute" is just a matter of optimizing the sieving effect of the polymer.

Addressing claim 11, for the additional limitation of this claim see Durr col. 10:36-49 and col. 10:59-62.

Addressing claim 14, for the additional limitation of this claim see Durr col. 4:31-61 and col. 10:59-62.

Addressing claims 22-24, for the additional limitations of these claims note that Johnson discloses at least hydroxyethylcelluslose. See col. 6:25-29. The other listed polymers were also used as electrophoresis separation media at the time of the invention. It was within the skill of one with ordinary skill in the art at the time of the invention to select the optimum separation polymer from known separation polymers.

8. Claims 1, 3-5, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yeung et al. (US 5,006,210) ("Yeung") in view of Johnson et al. (EP 077325 A2) ("Johnson"), the CAPLUS abstract of Barkas et al. ("Use of polyacrylamide gel electrophoresis for the preparation of oriented virus particle preparations," Doklady Akademii Nauk SSR (1979), 245(3), 736-9 (Biochem.) ("Barkas"), Silman (US 4,526,865) ("Silman"), and Catsimpoolas (US 4,375,401) ("Catsimpoolas').

Addressing claim 1, Yeung discloses a process for separating and identifying intact sample components while maintaining the sample components intact comprising:

(a) obtaining sample (implied by col. 3:49-50 and col.6:60-61);

(b) introducing the sample into a passageway having a fluid therein (col. 3:49-50 and col.6:60-61);

(c) separating one or more sample components in the fluid by means of an capillary electrophoresis so as cause the one or more sample components to move in the fluid and to separate one from another and from other components in said sample (col. 3: 51-54 and col. 7:44-47; and

(d) analyzing the separated sample components so as identify the sample components

(col. 3:60-66 and col. 7:44-60).

Yeung does not disclose an example embodiment in which intact microbes/cells are separated and identified; however, it would have been obvious to one with ordinary skill in the art at the time the invention was made to also use Yeung's method for separating and identifying intact microbes/cells because Yeung states, "The procedure of the invention is thus useful in the

genetics field, studying metabolism, and even having direct analysis of cells in vivo in clinical applications. Viruses and bacteria can be studied as well as other difficult to detect and analyze substances." See col. 6:15-20.

Yeung does not disclose adding a dilute water soluble polymer that focuses the microbes in the passageway during the separating step. However, at the time of the invention it was known to use a gel while electrophoresis microbes/cells. See Barkas and the abstracts of Silman and Catsimpoolas. At the time of the invention it was also known to add to an electrophoresis capillary a dilute water-soluble polymer that focuses biomolecules in the passageway during the separating step. See, for example, col. 3:34 – col. 4:11 in Johnson. Thus, whether a separation medium is used, such as gel or water-soluble polymer, while separating the microbes/cells, barring a showing to the contrary, such as unexpected results, is just a matter of optimizing the separation of the microbes/cells as this was a known purpose for using gels or uncrosslinked polymer solution during electrophoresis. Whether the water-soluble polymer is "dilute" is just a matter of optimizing the sieving effect of the polymer.

Addressing claim 3, for the additional limitation of this claim see the Yueng abstract and the figure.

Addressing claim 4, for the additional limitation of this claim see the Yeung abstract and figure.

Addressing claim 5, Yeung does not specifically mention any of the substrates listed by Applicant; however, the list is so comprehensive that it covers any natural source of microbes/cells and many man-made sources and so significantly overlaps or is effectively is as broad as the range of sources of microbes/cells contemplated by Yeung in his statement, "Viruses and bacteria can be studied [with his invention]..."(col. 6:15-19). Indeed the limiting of the substrate to soil or animal, for example, would not necessarily render Yeung unobvious with regard to this limitation.

Addressing claim 22, for the additional limitation of this claim note that Johnson discloses at least hydroxyethylcelluslose. See col. 6:25-29. The other listed polymers were also used as electrophoresis separation media at the time of the invention. It was within the skill of one with ordinary skill in the art at the time of the invention to select the optimum separation polymer from known separation polymers.

9. Claims 15-17 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCormick et al. (US 6,613,211 B1) ("McCormick") in view of Johnson et al. (EP 077325 A2) ("Johnson") and Grant et al. (GB 2348504 A) ("Grant").

Addressing claim 15, McCormick discloses a process for determining the viability of microbes/cells comprising

(a) obtaining a sample containing one or more intact microbes/cells from a substrate containing the microbes or cells (col. 12:38-40);

(b) dyeing the sample with a dye that causes viable microbes/cells to be distinguished from non-viable micros/cells (col. 12:47-49 and col. 11:10-16); and

(c) introducing the dyed sample into a passageway having a fluid therein (col. 11:26-27);

(d) separating the one or more microbes/cells in the fluid by means of an capillary electrophoresis so as to cause the one or more microbes to move in the fluid and to separate one from another and from other components in said sample while maintaining the microbes intact (implied by col. 11:53-55 and col. 13:26-30, which discloses applying EOF (electrosmotive force) and voltage differentials to the channel, which are of capillary dimensions (col. 13:1-14). Note that although not stated, barring a contrary showing, separation will inherently occur among fluid components that have different electrophoretic motilities).

McCormick does not specifically mention analyzing the separated intact microbes/cells so as to identify viable microbes/cells from non-viable microbes/cells based on the dye. However, it would have been obvious to one with ordinary skill in the art at the time the

invention was made to do so because McCormick teaches determining cellular response to toxic agents by using vital dyes to mark cells killed by the toxic agents. See col. 12:36-49.

McCormick does not disclose adding a dilute water soluble polymer that focuses the microbes in the passageway during the separating step, although it should be noted that McCormick discloses adding a water soluble polymer as a coating the capillary walls to modify any electrosomotic force that may occur during electrophoresis. See col. 5:1-12. At the time of the invention it was known to add to an electrophoresis capillary a dilute water-soluble polymer that focuses biomolecules in the passageway during the separating step. See, for example, col. 3:34 – col. 4:11 in Johnson. More especially, it was known at the time of the invention to add a dilute water-soluble polymer that focuses microbes in the passageway during the separating step. See in Grant the abstract; second full paragraph on page 18 and Example 9, which begins on page 30. It would have been obvious to one with ordinary skill in the art at the time of the invention to add a dilute water soluble polymer as taught by Grant in the invention of McCormick because it was known that dilute water soluble polymers can enhance separation of large biomolecules and so would be expected to enhance separation of microbes and because more especially, as shown by Grant, the separation of the microbes from each other can be optimized (Figures 13 and 14). Whether the water-soluble polymer is "dilute" is just a matter of optimizing the sieving effect of the polymer.

Addressing claim 17, for the limitation of this claim see McCormick Figures 1-3 and col. 13:1-16.

Addressing claim 25, for the additional limitation of this claim note that Johnson discloses at least hydroxyethylcelluslose. See col. 6:25-29. The other listed polymers were also used as electrophoresis separation media at the time of the invention. It was within the skill of one with ordinary skill in the art at the time of the invention to select the optimum separation polymer from known separation polymers.

10. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fuhr et al. (US 6,833,0610 ("Fuhr").

Fuhr discloses a process for separating and identifying intact particles while maintaining the particles intact comprising

(a) obtaining a sample comprising one or more intact particles (implied since a sample is separated);

(b) introducing the sample into a passageway having a fluid therein (col. 6:7-34);

(c) separating the one or more particles in the fluid by capillary isoelectric focusing so as to cause the one or more micros/cells to move in the fluid and to

separate from one another and from any other components in the sample while maintaining the particles intact (Figure 1; col. 5:8-9 and col. 6:35 – col. 7:5); and

(d) analyzig the separated intact particles so as to identify the particles (col. 7:1-5 and col. 8:59-67),

wherein the fluid comprises an ampholyte that focuses the microbes in the passageway during the separating step (col. 6:3-6; col. 4:16-37).

While Fuhr does not have an example in which the particles are intact microbes or cells it would have been obvious to one with ordinary skill to use his method to isoelectrically separate microbes or cells because Fuhr clearly contemplates such a use:

> Isoelectric separation according to the invention can be implemented with ampholytc molecules or all other synthetic or biological particles (especially cells or viruses) that exhibit electrical characteristics like those of ampholytic molecules, in particular a net charge or charge density that is a pH function of the surroundings [emphasis added]. *See col. 4:16-21.*

> The method according to claim 1, wherein the particles to be separated comprise ampholytic molecules or other particles, synthetic particles or biological cells, viruses, or other biological objects whose exhibit electrical characteristics correspond to the electrical characteristics of ampholytic molecules [emphasis added]. *Claim 2.*

Allowable Subject Matter

11. Claims 27-29 are allowed.

12. The following is a statement of reasons for the indication of allowable subject matter:

a) Claim 27; the combination of limitations requires "obtaining a sample containing one or more intact microbes from an organism stricken with a disease caused by said microbe" and "associating said microbe with a disease so as to diagnose said disease." Fuhr does not mention any sources for the microbes nor diagnosing a disease.

b) Claim 28; the combination of limitations requires "combining the sample with a drug or other substance in a fluid media to form a suspension and to allow said microbe/cell to bind with said drug/other substance." Fuhr does not disclose binding the microbe/cell to a drug/other substance. Fuhr arguably teaches away from such a step since his method is a purification method. See col. 2:31-46.

c) Claim 29; the combination of limitations requires "dying said sample with a dye that causes viable microbes/cells to be distinguished from non-viable microbes/cells." Fuhr does not disclose dying the microbes/cell. Fuhr arguably teaches away from such a step since his method is a purification method. See col. 2:31-46.

Final Rejection

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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